

REMARKS

Claims 43-61 have been canceled without prejudice or disclaimer. Claims 62-81 have been added and therefore are pending in the present application. Claims 62-81 are supported by claims 43-61.

The specification has been amended to specify the positions in SEQ ID NO: 2 which correspond to the mature enzyme and the catalytic domain, as shown in the Sequence Listing mailed on January 30, 2003.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Rejection of Claims 43-61 under 35 U.S.C. 101

Claims 43-61 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 43-61 have been rewritten as claims 62-81 to address this rejection. Applicants therefore submit that this rejection has been overcome.

II. The Rejection of Claims 43-61 under 35 U.S.C. 112

Claims 43-61 are rejected under 35 U.S.C. 112 as being indefinite. Specifically, the Office stated that "Claim 43 is rejected because of the confusion in the claimed amino acid residue numbers of SEQ ID NO: 2."

Applicants submitted in a corrected Sequence Listing on July 30, 2003, in which the signal peptide of the beta-1,4-endoglucanase is set forth as amino acids -29 to -1. The specification is amended herein to specify the amino acids of the mature enzyme (amino acids 1-456) and of the catalytic domain (amino acids 457-617). Applicants therefore submit that this rejection has been overcome.

III. The Rejection of Claims 43-48 and 54-60 under 35 U.S.C. 112

Claims 43-48 and 54-60 are rejected under 35 U.S.C. 112 because the specification ... does not reasonably provide enablement for any [beta-1,4-endoglucanase] enzyme that has 75%, 80%, 85%, 90%, 95%, or 98% sequence identity with amino acids 1-456 or 1-617 of SEQ ID NO: 2...." This rejection is respectfully traversed.

It is well settled that "a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of section 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971).

Moreover, "[a]ny assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed." *In re Dinh-Nguyen*, 181 U.S.P.Q. 46, 47 (C.C.P.A. 1974). Thus, the burden is upon the Patent Office to set forth reasonable grounds in support of its contention that a claim reads on inoperable subject matter). See *In re Stark*, 172 U.S.P.Q. 402, 406 n. 4 (C.C.P.A. 1972).

Applicants submit that the specification fully enables one skilled in the art to practice the claimed inventions.

The claims are drawn to polypeptides having beta-1,4-endoglucanase activity which have an amino acid sequence that is at least 85% identical with one or more of the sequences of amino acids 1-456 or 1-617 of SEQ ID NO: 2 and/or which are encoded by a DNA sequence that hybridizes to nucleotides 76-1455 of SEQ ID NO: 1 under high stringency conditions.

The specification contains an extensive disclosure of how one skilled in the art can make and use the polypeptides of the present invention. For example, the specification describes hybridization techniques as well as mutagenesis to produce polypeptides of the present invention. These techniques are well known in the art and are routine for the skilled artisan.

Moreover, on the basis of Applicants' disclosure, one skilled in the art would know where to search for strains in order to obtain other beta-1,4-endoglucanase of the present invention. Methods for screening strains to find ones which produce enzymes with desired characteristics are well known. Indeed, these screening methods are routine for persons skilled in the art. Applicants, therefore, submit that the specification combined with the knowledge of the art provides sufficient guidance to one skilled in the art to isolate nucleic acid sequences encoding beta-1,4-endoglucanases.

The facts in the present case are similar to those in *In re Wands, supra*. There, the claimed invention involved methods for the immunoassay of hepatitis B surface antigen (HBsAg) by using high-affinity monoclonal IgM antibodies having specified properties. A hybridoma cell line that secretes IgM antibodies against HBsAg was deposited at a recognized

cell depository. The claims, which were not limited to the deposited cell line, were rejected for lack of enablement. The Federal Circuit reversed the rejection as follows:

When Wands' data is interpreted in a reasonable manner, analysis ... leads to the conclusion that undue experimentation would not be required to practice the invention. Wands' disclosure provides considerable direction and guidance on how to practice their invention and presents working examples. There was a high level of skill in the art at the time when the application was filed, and all of the methods needed to practice the invention were well known.

The nature of monoclonal antibody technology is that it involves screening hybridomas to determine which ones secrete antibody with desired characteristics. Practitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody. No evidence was presented by either party on how many hybridomas would be viewed by those in the art as requiring undue experimentation to screen. However, it seems unlikely that undue experimentation would be defined in terms of the number of hybridomas that were never screened.

In re Wands, 8 U.S.P.Q.2d at 1406-07.

Applicants also respectfully submit that requiring applicants to limit the claims to the specific beta-1,4-endoglucanase would be contrary to public policy as set forth in *In re Goffe*, 191 U.S.P.Q. 429, 431 (C.C.P.A. 1976):

For all practical purposes, the board would limit appellant to claims involving the specific materials disclosed in the examples, so that a competitor seeking to avoid infringing the claims would merely have to follow the disclosure in the subsequently-issued patent to find a substitute. However, to provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for 'preferred' materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

In the instant case, claims limited to the specific beta-1,4-endoglucanase would not adequately protect the inventors. Based on the teachings of the present application, one skilled in the art would attempt to find other beta-1,4-endoglucanases and thereby attempt to circumvent the literal scope of Applicants' patent rights.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. The Rejection of Claims 43-58 and 60-61 under 35 U.S.C. 102

Claims 43-58 and 60-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Dhillon et al. (Biotechnology Letters, Vol. 7, No. 9, pp. 695-697 (1985), a copy of which is enclosed herewith). This rejection is respectfully traversed.

Dhillon et al. disclose an endoglucanase from *Bacillus licheniformis*-1, which has a temperature optimum of 55°C.

However, Dhillon et al. do not disclose an endoglucanase having a temperature optimum of 65°C, as claimed herein.

Moreover, Dhillon et al. have not deposited *Bacillus licheniformis*-1. Therefore, the Dhillon et al. reference is non-enabling.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102. Applicants respectfully request reconsideration and withdrawal of the rejection.

V. The Rejection of Claim 59 under 35 U.S.C. 103

Claim 59 is rejected under 35 U.S.C. 103 as being unpatentable over Dhillon et al. in view of Olsen et al. (WO 95/26398). This rejection is respectfully traversed.

The Dhillon et al. reference is addressed in Section IV above. Applicants submit that Olsen et al. fail to cure the deficiencies of Dhillon et al.

Olsen et al. disclose modified cellulases and compositions comprising a cellulase.

However, Olsen et al. also do not teach or suggest the endoglucanases of the present invention.

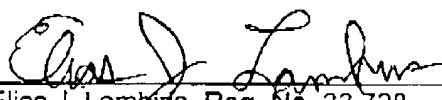
For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

VI. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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